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By:

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PATENT
Customer Number: 22,852
Attorney Docket No. 04853.0079-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Kazunari TAIRA et al.) Group Art Unit: 1635
Application No.: 09/974,974) Examiner: Jane J. Zara
Filed: October 12, 2001) Confirmation No. 2692
For: NUCLEIC ACID ENZYMES)
ACQUIRING AN ACTIVITY)
FOR CLEAVING A TARGET)
RNA BY RECOGNIZING)
ANOTHER MOLECULE)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

Applicants now respond to the Office Action mailed July 1, 2004. A Petition for a Two Month Extension of Time and the requisite fee are filed herewith.

In the Office Action, the Examiner vacated the prior restriction requirement dated February 5, 2004, and imposed a new restriction requirement. Specifically, the Examiner required election of "**ONE nucleotide construct** comprising the combination of: one dimer pair from claim 9 or 11, one promoter sequence from claim 15, one

additional sequence from claim 19, and one target gene from either claim 4, 5, 6, 8, 10, 11 or 28." Office Action at page 3.

Applicants elect the following:

- 1) the dimer pair of SEQ ID NO:1 and SEQ ID NO:2 (Claim 9);
- 2) the promoter sequence of SEQ ID NO:5 (which is the only promoter sequence recited in Claim 15)¹;
- 3) the additional sequence of 5' UUUUU 3' (from Claim 19); and
- 4) the target gene of "an mRNA encoding a protein associated with a disease such as cancer" (from Claim 5).

Claims 1, 2, 5, 8-12, and 15-30 read on the elected species. See M.P.E.P. § 809.02(a) at 800-49 (8th ed. rev. 2, May 2004). "An examiner's action subsequent to an election of species should include a complete action on the merits of all claims readable on the elected species." *Id.* § 809.02(c) at 800-50.

Applicants respectfully traverse the restriction requirement on the grounds that a search of the claims would not pose a serious burden on the Examiner. See *id.* § 803 at 800-4 ("If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits....").

The Examiner alleges that all possible combinations of a "dimer pair" (claim 9 or claim 11) with a promoter sequence (claim 15) and an additional sequence (selected from claim 19) represent "different and specific" nucleic acid sequences. Office Action at page 2. The Examiner further alleges that "each target gene listed by name, in

¹ Applicants note that the Examiner incorrectly asserts that claim 15 recites "various" tRNA^{val} promoter sequences, but in fact, this claim recites only a single sequence (SEQ ID NO:5).

combination with one dimer pair, one promoter sequence and one additional sequence, comprises a specific nucleic acid construct.” *Id.* at pages 2-3. The Examiner concludes that “a search of all the sequence combinations and target regions claimed presents an undue burden on the Patent and Trademark Office to search and examine.” *Id.* at page 3.

Applicants disagree with the Examiner for the following reasons: First, only six different nucleic acid sequence combinations (comprising a dimer pair, a promoter, and an additional sequence) are possible. Specifically, three different sequences are generated by combining the dimer pair of claim 9 and the promoter of claim 15 with each of the three sequences of claim 19. An additional three sequences are generated by combining the dimer pair of claim 11 and the promoter of claim 15 with each of the three sequences of claim 19.

Furthermore, a search that establishes the patentability of one of the dimer pairs, e.g., the dimer pair of claim 9, would establish the patentability of all sequence combinations comprising that dimer pair. The same holds true for a search that establishes the patentability of the dimer pair of claim 11. Thus, the Examiner need only search the two sets of dimer pairs to establish the patentability of all sequence combinations comprising those dimer pairs. This would not pose a serious burden on the Examiner.

Applicants also disagree with the Examiner’s assertion that it would be an undue burden to examine the nucleic acid sequences of claims 9, 11, 15, and 19 in combination with the listed “target genes.” By “target genes,” the Examiner is presumably referring to the target RNAs recognized by the claimed nucleic acid

enzymes. Those target RNAs merely describe the specificity of the claimed nucleic acid enzymes. *They do not require the Examiner to search additional nucleic acid sequences*, as the Examiner appears to argue. Office Action at pages 2-3 (alleging that “each target gene listed by name, in combination with one dimer pair, one promoter sequence and one additional sequence, comprises a specific nucleic acid construct”).

Applicants note that the Examiner incorrectly states that the “target genes” are listed in claims 4, 5, 6, 8, 10, 11, and 28. Indeed, claims 3 (not listed by the Examiner), 4, 5, 8, 10, and 28 encompass specific embodiments of target RNAs recognized by the claimed nucleic acid enzymes. Claim 11, however, is directed to a specific embodiment of a nucleic acid enzyme having a specific “sensor site,” and claim 6 is directed to an RNA that binds to the sensor site of a nucleic acid enzyme.

Applicants also note that the Examiner did not mention claims 1-3, 7, 12-14, 16-18, 20-27, and 29-30 in the restriction requirement. Therefore, those claims, which include generic claims, are presumably not subject to restriction and are under consideration. Consequently, the nonelected species should no longer be held withdrawn if a claim generic to the nonelected species is allowed. See M.P.E.P. § 809.02(c)(B)(1) at 800-50.

Please grant any extensions of time required to enter this response and charge
any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: October 1, 2004

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